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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,364

02/14/2006

Lawrence J. Saubermann

BU-101XX

1148

207 7590 01/07/2009
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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

01/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,364	Applicant(s) SAUBERMANN ET AL.	
	Examiner David A. Saunders	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/17/08</u> . | 6) <input type="checkbox"/> Other: _____ |

AMENDMENT ENTRY

Amendment of 9/24/08 has been entered. Claims 1-9 are pending. Claims 1-9 are under examination.

OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN

The amendment has overcome previously stated issues as follows:

The objection to claim(s) 14 under 37 CFR 1.75, since claim 14 has been cancelled.

The rejection of claim(s) 1-14 under 35 USC 112, 2nd paragraph.

The rejection of claim(s) 1-14 under 35 USC 112, 1st paragraph.

The 102 prior art rejection of claim(s) 10-14 based upon Romaschin et al, since claims 10-14 have been cancelled.

The 102 prior art rejection of claim(s) 10-14 based upon Rang et al, since claims 10-14 have been cancelled.

The 103 prior art rejection of claims 1, 4 and 6-9 over Marie et al in view of Levinson. Marie et al teach samples of isolated PBMs, rather than samples of whole blood.

NEW REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A step of centrifuging the plasma or serum from the whole blood sample, between the "incubating" step and the "assaying" step of claim 1, is critical or essential to the practice of the invention; but this step has not been included

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in the claim(s). The claimed invention is thus not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant has disclosed such centrifuging step at page 5, lines 25-30, but has not included this step in the claim.

Since claim 1 now requires a incubating step that uses whole/unfractionated blood, it is essential that applicant recite the centrifuging step, because, in fact, it is not the whole blood incubated sample that is assayed in the final step.

MAINTAINED REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not given an adequate description of “any metabolized portion of said pro-inflammatory substance”.

This basis of rejection was previously stated on the basis that applicant had not given an adequate description of “a metabolic product of said pro-inflammatory substance”. Presently claim 8 recites “any metabolized portion” in lieu of “a metabolic product”. However applicant has given no description of any such “metabolized portion” of any of the pro-inflammatory substances. As previously stated, any protein can metabolically breakdown to its constituent amino acids. Are amino acids among the “metabolized portions”? One has no idea what the genus of “metabolized portions” encompasses.

MAINTAINED PRIOR ART REJECTION(S)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4 and 6-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Setrakian et al (cited on PTO-1449 of 10/17/08).

Setrakian et al teach that whole blood samples, obtained from a subset of patients with sepsis, that are stimulated with LPS have a lowered production of TNF-alpha. See abstract and page 188, cols. 1-2. Applicant has taught that TNF-alpha is associated with a Th-1 response. Applicant has taught that LPS induces a Th-1 response. Thus it is inherent that what Setrakian et al teach reflects a Th-1 response. From these considerations, instant claims 1, 4 and 6-7 are anticipated.

Regarding claim 3, Setrakian et al teach that, in some experiments, interferon gamma was added, along with the LPS, as a stimulant. Since the scope of the claims is open, the inflammatory stimulant according to the method of claim 3 can contain an additional component, such as LPS.

Regarding instant claims 8-9, Setrakian et al teach that the TNF-alpha is detected by an ELISA method. See abstract and page 189, col. 2.

FINALITY

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 10/17/08 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**

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MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONTACTS

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 1/3/09 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644